

USSN: 10/748,524  
Attorney Docket: 1-1995.184 US D1  
Response to Office Action of October 17, 2005

Amendments to the Claims:

1. (Currently amended) A multicomponent vaccine for cattle comprising an immunogenically effective combination of a protective antigen component from at least six clostridial organisms, a protective antigen component from at least one non-clostridial organism, which is *Moraxella Bovis* (*M. Bovis*) and an at least one adjuvant selected from the group consisting of oil -in- water, water-in-oil, Al (OH)<sub>3</sub>, Al<sub>2</sub>(SO<sub>4</sub>)<sub>3</sub>, Al PO<sub>4</sub>, bacterial extracts, a plant extract, a polymer and a liposome, wherein the vaccine is in a low dose volume of about 2 ml or less.
2. (Currently amended) A multicomponent vaccine for cattle, comprising an immunogenically effective combination of protective antigen components from at least seven clostridial organisms, a protective antigen component from at least one non-clostridial organism, which is *M. Bovis*, and an at least one adjuvant selected from the group consisting of oil -in- water, water-in-oil, Al (OH)<sub>3</sub>, Al<sub>2</sub>(SO<sub>4</sub>)<sub>3</sub>, Al PO<sub>4</sub>, bacterial extracts, a plant extract, a polymer and a liposome, wherein the vaccine is in a low dose volume of about 2 ml or less.

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3. (Currently amended) The vaccine according to Claim 1, wherein the clostridial organism is selected from the group consisting of *Clostridium chauvoei*, *Clostridium septicum*, *Clostridium novyi*, *Clostridium perfringens* type C, *Clostridium perfringens* type D, *Clostridium sordellii*, *Clostridium haemolyticum* *haemolyticum* and *Clostridium tetani*.

Claims 4-14 Cancelled

15. (Previously presented) The vaccine according to Claim 3, wherein the 6 clostridial organisms are selected from the group consisting of *Cl. chauvoei*, *Cl. septicum*, *Cl. novyi*, *Cl. perfringens* type C, *Cl. perfringens* type D, *Cl. haemolyticum* and *Cl. sordellii*.

16. (Cancelled)

17. (Previously presented) The vaccine according to Claim 2, wherein the 7 clostridial organisms are selected from the group consisting of *Cl. chauvoei*, *Cl. septicum*, *Cl. novyi*, *Cl. perfringens* type C, *Cl. perfringens* type D, *Cl. sordellii*, *Cl. haemolyticum*, and *Cl. tetani*.

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18. (Previously presented) The vaccine according to Claim 1,  
wherein the protective antigen component from 6 clostridial  
organisms is from *Clostridium chauvoei*, *Clostridium septicum*, *Clostridium novyi*,  
*Clostridium perfringens* type C, *Clostridium perfringens*, type D, and *Clostridium sordellii*.

19. (Previously presented) The vaccine according to claim 2,  
wherein the protective antigen component from 7 clostridial  
organisms is from *Clostridium chauvoei*, *Clostridium septicum*, *Clostridium novyi*, *Clostridium perfringens* type C, *Clostridium perfringens*, type D, *Clostridium haemolyticum* and *Clostridium sordellii*.

Claims 20-39 Canceled

40. (Currently amended) The vaccine according to claim 2,  
wherein the 7 clostridial organisms are *Clostridium chauvoei*, *Clostridium septicum*, *Clostridium novyi*, *Clostridium perfringens* type C, *Clostridium perfringens* type D, *Clostridium sordellii* and *Clostridium haemolyticum* and the  
protective antigen component from at least one non-  
clostridial organism comprises *Haemophilus somnus* and *Mycoplasma bovis*.

Claims 41-45 (Canceled)

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46. (Previously presented) A method of immunizing an animal comprising administering an effective amount of the vaccine of Claim 1.

47. (Previously presented) A method of immunizing an animal comprising administering an effective amount of the vaccine of Claim 2.

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In the office action of October 17, 2005, the Examiner rejected claims 1-3, 11, 15, 17-19, and 40 under 35 U.S.C. 102(a) for being anticipated by Roberts (WO94/22476).

Applicants wish to point out that Roberts (WO94/22476) ultimately issued as US Patent 6,083, 512 on July 4, 2000.

Applicants respectfully submit that the ranges of vaccine dosage relied on by the Examiner (0.5 ml to 10ml) and the non-clostridial component, *Moraxella bovis*, are merely mentioned in passing and no vaccine compositions are described specifically comprising *Moraxella bovis* or dosages except 5ml (see example). These general statements regarding broad possibilities stated as general dosage ranges and a multiplicity of non-clostridial antigens, without teaching clostridial combinations with *Moraxella bovis* or vaccines of any sort in dosage sizes except 5 ml, did not constitute anticipation as they do not place in the hands of the ordinary practitioner a low dose, e.g., 2ml, vaccine combination with, in addition to a multi way clostridial vaccine, a *Moraxella bovis* antigen.

The Roberts invention is the use of a saponin as an adjuvant in place of an aluminum compound previously used in the art. The purpose of this is to reduce site inflammation and the consequent meat spoilage that was experienced using conventional vaccines. This, Roberts believed, was achieved by using saponin antigens. There is no suggestion of achieving the same result by using low dose vaccines. Applicants discovered they could achieve the same result by reducing the size of the dosage, and in the present claims achieved that with a clostridial combination that contained, in addition, a *Moraxella bovis* antigen.

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It is submitted that the present invention is neither anticipated nor obvious in the view of the teaching of the Roberts publication. Nevertheless, for purposes of advancing the prosecution of this application, Applicants are now submitting amendments to the claims reciting a specific group of adjuvants to be used in the multicomponent, low dose, combination vaccines. Saponins are not included among the adjuvants that may be selected.

In view of the present amendments, it is respectfully submitted that the vaccines now claimed are neither anticipated nor obvious in the view of Roberts. In fact, Roberts teaches against the selection of adjuvants recited in Applicants' claims.

As all adjuvants previously recited in claim 11, with the exception of a saponin, are now introduced as Markush groups limiting the independent claims, it is respectfully submitted that no additional review or examination is necessary to consider the present amendments. Entry of these amendments and allowance of claims 1-3, 15, 17-19, 40, 46 and 47 is respectfully requested.

Should the Examiner consider that a conference would be helpful in advancing the prosecution of this application, she is invited to telephone Applicants' attorney at the number below.

If necessary, the Commissioner is hereby authorized in this concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2334 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17.

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Respectfully submitted,



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CERTIFICATE OF FACSIMILE

I certify that this correspondence is being sent via facsimile on December 1, 2005 to facsimile no. (571) 273-8300 to the attention of Examiner Hines, Jana A, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

